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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,850	03/29/2001	Michael P. Bevilacqua	2331/112US	3553

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EXAMINER

ALLEN, MARIANNE P

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,850

Applicant(s)

BEVILACQUA ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/27/03; 6/26/03; 7/21/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 187-205 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 187-194 is/are allowed.
- 6) ☒ Claim(s) 195-205 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 5/27/03; 7/21/03 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17-19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to amendments submitted 5/27/03 (Paper No. 22), 6/26/03 (Paper No. 24), and 7/21/03 (Paper No. 26).

Claims 1-186 have been cancelled. Claims 187-205 have been newly introduced.

The rejection of claims 167-179 under 35 USC 112, first paragraph, with respect to new matter and enablement (as it concerns developing primer-probe sets) is withdrawn in view of the amendments to the claims and the Tryon Declaration under 37 CFR 1.132 filed 5/27/03 (Paper No. 21).

The rejection of claims 167, 169-173, 175, 177-178 under 35 U.S.C. 102(a) as being anticipated by Rodriguez-Antona et al. (Archives of Biochemistry and Biophysics, 376(1):109-166, 2000) is withdrawn in view of amendments to the claims.

While basis for claim 204 was not found on page 28, lines 14-17, as stated in the response, support for this subject matter was found on page 30, lines 21-27.

Information Disclosure Statement

The information disclosure statements submitted 12/31/02 (Paper No. 17), 1/17/03 (Paper No. 18, copy of IDS originally submitted 5/10/01), and 5/11/03 (Paper No. 19) have been considered and the initialed forms are attached.

Specification/Drawings

The corrections to the specification and drawings are noted.

Applicant has inserted "Polynucleotide kinase 3' phosphatase" into Table 2 as the definition for PNKP. Applicant asserts that one of ordinary skill in the art would know that PNKP is the name for gene well-known in the art. Applicant did not provide any documentation

in support of this assertion. Applicant is reminded that such statements must be supported to preclude new matter objections or rejections. To expedite prosecution of the instant application, the examiner provides evidence that PNKP would have been a well known polynucleotide kinase 3' phosphatase. See Jilani et al. (Journal of Biological Chemistry, 274(34):24176-24186, 1999).

A complete set of corrected and substitute drawings was received on 5/27/03 (Paper No. 20).

Drawings containing further corrections to Figure 13d and Figure 14 were received on 7/21/03 (Paper No. 26).

Figures 1-9, 10a, 10b, 11a, 11b, 12a, 12b, 13a-13c, 15, 16a-16b, 17, 18a-18e, 19a-19b, 20-24, 25a-25c, 26a-26d, 27a-27d, 28a-28d, 29a-29b, and 30-36 as submitted 5/27/03 (Paper No. 20) and Figures 13D and Figure 14 as submitted 7/21/03 (Paper No. 26) have been accepted and form a complete set of the drawings. There are a total of 49 sheets of drawings.

Claim Rejections - 35 USC § 112

Claims 195-205 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claim 195 recites "wherein the profile data set characterizes a biological condition." The specification fails to define the metes and bounds of what constitutes a biological condition and/or what is considered to characterize it.

It is considered to be an invitation to experiment to determine the combinations of at least four constituents from any one of Tables 1 through 7 (and further including unspecified

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additional constituents embraced by the claims) that would characterize a biological condition in the absence of further guidance. For example, the specification does not disclose what biological condition, if any, is characterized by determining a profile data set comprising TERT, BCL2, BAX, and MADD (see Table 2). Would this be a different biological condition from a profile data set comprising TERT, BCL2, BAX, MADD, and cdk4 or a profile data set comprising TERT, BCL2, BAX, MADD, and CASP 3? Likewise, if the biological condition of interest is breast cancer or alcoholism, the specification does not disclose which, if any, combinations of at least four constituents from any one of Tables 1 through 7 would characterize either of these conditions.

It is further noted that the specification clearly discloses the requirement for at least half and preferably at least 80% of the named constituents when evaluating a biological condition. (See at least pages 9-10 of the specification.)

Claim 203 recites “wherein the biological condition being evaluated.” For the reasons set forth in the prior Office action, the method as written does not result in evaluating a biological condition and as such, this method is not enabled. The specification does not disclose how a biological condition is determined to be “with respect to a localized tissue” and what constitutes a “tissue or fluid of a type distinct from that of the localized tissue.” Specific examples of liver metabolism and blood samples does not provide guidance commensurate in scope with the claims. For example, what is the localized tissue considered to be for the biological condition of alcoholism? The brain, the liver, the skin? What is the localized tissue considered to be for the biological condition defined by the profile data set comprising TERT, BCL2, BAX, MADD, and cdk4? The specification provides no guidance.

Claims 195-205 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 195 recites “wherein the profile data set characterizes a biological condition.” Claims 196-202 recite a biological condition. It cannot be determined from the specification what the metes and bounds of a biological condition are and/or what is considered to characterize it. If applicant considers that all combinations of at least four constituents from any one of Tables 1 through 7 characterize a biological condition, then this claim is not properly dependent as it would fail to further limit the subject matter of claim 187. Furthermore, the metes and bounds of a “skin response” (claim 199) are not known. That is, does this claim embrace contact dermatitis, psoriasis, leprosy, and bruising? The metes and bounds of the conditions embraced by claims 196-198 and 200-202 are likewise unknown.

Claim 196 refers to Table 1 and inflammation. Claims 197-202 depend upon claim 196 but refer to different Tables and biological conditions. As such, claims 197-202 are confusing and appear to be improperly dependent. It appears that applicant may have intended for them to depend upon claim 195.

Claim 203 recites “wherein the biological condition being evaluated.” However, the claims upon which it depends are not directed at evaluating a biological condition.

Conclusion

Claims 187-194 are allowable. Applicant is advised that the rejections to claims 196-202 could be obviated by making these claims dependent upon claim 187 and amending the claim

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language as follows: "A method according to claim 187, wherein the at least four constituents are selected from Table X." Amending claims 196-202 in this manner would make claims 204-205 allowable. Alternatively, if claims 204 and 205 did not depend from claims 196-202, they would be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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A handwritten signature in cursive script that reads "Marianne P. Allen".

Marianne P. Allen

Primary Examiner

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mpa

August 5, 2003